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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/254,600	03/11/1999	YAROM COHEN	TPP30566	7243

7590 08/26/2004

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EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/254,600	COHEN, YAROM	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *110-122* is/are pending in the application.

4a) Of the above claim(s) *117,118 and 122* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *110-116 and 119-121* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment, filed 6-1-04 is acknowledged. Claims 119-122 were added to by the amendment. Claims 110-122 are pending in this application.

Applicant's election of Cyclo [N-Me-Ala-Tyr-D-Trp-Lys-Val-Phe] in Paper No. 17 is acknowledged. Claims 117 and 118 drawn to diazoxide and metformin are hereby withdrawn.

Newly submitted claim 122 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The claim is drawn to a method for treating hypertension. This method is distinct from the original method of treating Syndrome X. The method is distinct because the method of treating hypertension may not necessarily have the same subject. Therefore, the method of claim 122 may involve different patients and thus is distinct from the method of claim 110.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 122 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

> to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 110-115 remain and new claims 119-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mogul et al. and Reaven in view of Orskov et al. and Verber et al for the reasons set forth in the previous office action and the reasons set forth below

The claims are drawn to a method of treating Syndrome X by the administration of somatostatin.

Applicants argue that there is a distinction between syndrome X and insulin resistance. Applicants make reference to page 1596 of Raven which states "insulin resistance, by itself, is not sufficient to produce the full blown syndrome [X]." Furthermore, Applicants argue that the conclusion in Reaven were based on normal rats and Reaven states "great care should be exercised in the extrapolation of results of studies in normal rats to humans with hypotension." Applicants state that "Reaven suggest that the data obtained from normal rates may not be applicable to humans with hypertension." Applicants reiterate that the reference only establishes a "casual relationship between insulin resistance and hypertension."

Applicants also argue that the application of Orskov et al. is in appropriate since this reference based on Insulin dependent diabetes Mellitus (IDDM). In IDDM patients there is a lack of insulin and no insulin resistance. Thus, the application of Orskov et al. is misplaced. Finally, the reference of Orskov et al. discloses a dosage that is significantly lower than that claimed in the instant application.

Applicant's arguments filed 6-01-04 have been fully considered but they are not persuasive.

First, Applicants arguments with regards to the rat model is unclear. As indicated by Ravaen et al., Syndrome X is associated with numerous abnormalities, such a s resistance to insulin- stimulated glucose uptake, glucose intolerance, hyperinsulinemia, increased very low density lipoprotein triglyceride and hypertension (see page 1605). Further, it should also be noted that the instant application is also based on animal models. Page 22-23 disclose the use of rat models and the effects of octeoride on rats. If the art is unpredictable for humans, then Applicants specification is also lacking ample guidance to provide prediction for human efficacy.

Never the less, the art still renders obvious the claimed invention. The Ravean reference disclose that controlling the resistance of insulin, "enable the treatment of all risk factors of syndrome X or Reaven simultaneously." The reference of Mogul et al. teach that "[h]yperinsulinemia is a manifestation of insulin resistance, a precursor to non-insulin diabetes mellitus (NIDDM) and the hallmark of Metabolic Syndrome X." (See page 4492).

Thus, insulin resistance is the hallmark of syndrome X. If one can control insulin resistance, one can effectively treat syndrome X. The specification echoes this sentiment by stating on page 2 "All of the risk factors of syndrome X of Raven are, inter alia, caused by a high resistance to Insulin. Thus, apparently said symptoms could be treated simultaneously if there would be reduction of the resistance to Insulin. . . ."

The art recognizes that somatostatin and octreotide infusion decreased insulin requirement and increased insulin sensitivity in IDDM patients (see Orskov et al. at page 215). Applicants have stated that IDDM patients lack insulin resistance. However, insulin resistance is a part of IDDM as it is a part of NIDDM. (see for example Yki-Jarvinen et al.). Therefore, since the art recognizes that insulin resistance is the hallmark of Syndrome X, it would have been obvious to use somatostatin to control insulin resistance, and thereby treat Syndrome X. Controlling insulin resistance would necessarily lead to the treatment of Syndrome X since all of the risk factors are connected to the treatment of insulin resistance.

Finally, for the dosage claimed, generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Thus, it would be obvious to optimize the dosage necessary to treat insulin resistance.

Therefore, the rejection is maintained.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action.

In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell, can normally be reached on (571) 272-0974. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

8/12/04

Anish Gupta
Patent Examiner

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SUPERVISORY PATENT EXAMINER
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